

The Innovative Company.

I have been upperfectioned have a supperfection of the innovative Company.

I have been upperfectioned have a supperfection of the innovative and the innovative and perfect to the innovative perfection.

The second secon

OCT 1 8 2004

October 5, 2004

Food & Drug Administration
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
200 C Street SW
Washington, DC 20204

Dear Sirs:

Notice is hereby given pursuant to the requirement of section 403 (r) (6) (21U.S.C. 343 (r) (6)) of the Federal Food, Drug and cosmetic Act and in accordance with the requirements of 21 CFR 101.93 that Lane Labs USA, INC. 25 Commerce Drive Allendale, NJ 07401 is marketing a dietary supplement bearing the following statement(s) on the label and/or on the labeling:

TEXT OF CLAIM:

"The Every-Other-Day Probiotic Dietary Supplement"

"Helps promote balance in your digestive system by increasing the population of helpful bacteria — microorganisms that help you break down and absorb the foods you eat."

"Has a special strain of Lactobacillus Fermentum PCC M which provides a minimum of 2 billion live organisms in each capsule with 90% viability that have been clinically shown to keep working for up to 48 hours."

NAME OF INGREDIENT: Lactobacillus Fermentum P.C.C.

NAME OF SUPPLEMENT: GI48

I certify that the information contained in this notice is complete and accurate and that Lane Labs USA, INC has substantiation that the statement is truthful and not misleading.

Sincerely.

Andrew Lane

President

97S 0162 LET

14757

89887